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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,026	12/16/2003	Steven N. Roe	7404-548	5585

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP  
111 MONUMENT CIRCLE, SUITE 3700  
INDIANAPOLIS, IN 46204-5137

EXAMINER
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NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/737,026

Applicant(s)

ROE, STEVEN N.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-30 is/are pending in the application.
- 4a) Of the above claim(s) 14-16, 26 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-13, 17-25, 27-29 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/16/03, 6/1/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election **without** traverse of Invention II and Species 1 drawn to **Claims 10-13, 17-25, and 27-29** in the reply filed on 4/19/2006 is acknowledged.
2. **Claims 14-16, 26, and 30** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species. **Claims 1-9** are cancelled.

### ***Priority***

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged, namely, priority to provisional application 60437002, filed on 12/23/2002.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on 12/16/2003 and 6/1/2004 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Specification***

5. The disclosure is objected to because of the following informalities:  
    "sampling mechanism 78" disclosed on p.12 line 13 of the specification should be "sampling mechanism 76";  
    "trigger 88" disclosed on p.12 line 26 of the specification should be "trigger 78."

Appropriate correction is required.

***Claim Objections***

6. **Claim 22** is objected to because of the following informalities: the word “to” is missing after “cam arm” and before “deflect.” Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. **Claims 10-13, 17-25, 27-29** are rejected under 35 U.S.C. 102(e) as being anticipated by Uchigaki et al (US Pat No. 6849052).

9. In regard to **Claims 10, 24, and 27-28**, Uchigaki et al disclose a body fluid sampling device best seen in Figure 2 comprising:

a lancet (31) configured to form an incision in skin (Col.7, line 38-46, 57-58);

a sampling mechanism, referred to as "biosensor" (36), having a sampling end, referred to as "body fluid path" (36b) (Col.7, line 65-67), best seen in Figure 2 left, disposed proximal to the lancet that is moveable between a first position over the incision, referred to as "retreated position" (Col.8, line 24-25), and a second position away from the incision, referred to as

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"advanced position" (Col.8, line 44-48), wherein the term "away" is relative and thus the advancement of said sampling mechanism is considered as such;

a deflection mechanism, referred to as "eccentric cam" (42), engageable with the sampling mechanism to deflect the sampling end of the sampling mechanism from the first position to the second position in order to allow the lancet to form the incision (Col.8, line 44-52);

wherein at least a portion of the sampling mechanism is inherently resilient because said sampling mechanism is movable from a first position to a second position, thus said sampling mechanism can also return to the first position after the incision is formed.

10. In regard to **Claims 11-13, and 19**, Uchigaki et al disclose the sampling mechanism (36) as a test strip fluid collection element that is inherently resilient, as described above (Col.8, line 46-56).

11. In regard to **Claim 17, 25, and 29**, Uchigaki et al disclose the deflection mechanism as a cam arm, referred to as "eccentric cam" (42) best seen in Figure 2, coupled to the lancet and capable of moving in unison with the lancet to deflect the test strip as described above (Col.4, line 64-67).

12. In regards to **Claim 18**, Uchigaki et al disclose the cam arm (42) has an angled surface, referred to as "bevel surface" best seen in Figure 2 (Col.7, line 15-20) that is engageable with the sampling mechanism (36) to deflect the sampling mechanism as described above.

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13. In regards to **Claim 20**, Uchigaki et al disclose a holder, referred to as "lancet holder" (30) defining:

a cam arm cavity, which resides between "bottom wall" (35) of said lancet holder (30) and in the vicinity of "round hole" (35e) (Col.6, line 52-57), which the cam arm (42) is slidably received, best seen in Figure 2 right side;

a fluid collection element cavity, which resides in the vicinity of "arcuate openings" (36f) and "bottom wall" (35) of said lancet holder (30) (Col.6, line 57-60), in which the fluid collection element (36) is received, best seen in Figure 2 middle (Col.5, line 46-48);

wherein the cam arm cavity intersects the fluid collection element cavity in that said cam arm cavity resides directly beside said fluid collection cavity.

14. In regards to **Claim 21**, Uchigaki et al disclose the holder (30) defining:

a lancet cavity, referred to as "cylindrical housing" (35b), in which the lancet (31) is slidably received, best seen in Figure 2 (Col.5, line 12-17);

a deflection cavity located to the left of said fluid collection element (36) and underneath said lancet (31) best seen in Figure 4, in which the fluid collection element is able to deflect as described above (Col.8, line 46-52) .

15. In regards to **Claim 22-23**, Uchigaki et al disclose the sampling end portion of said fluid collection element (36) angled at an acute angle relative to the lancet (31) (Col.8, line 50-52), as seen in Figure 2, to allow the cam arm (42) to deflect the fluid collection element before the lancet is able to strike the fluid collection element, as described above (Col.8, line 46-50).

*Conclusion*


16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mace et al (US Pub No. 20050277850), Matsumoto (US Pub No. 20050288698), and Sakata et al (US Pub No. 20040215224 and 20050261716) all disclose integrated lancing apparatuses.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HQN  
5/5/2006

  
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